

### **REMARKS**

The Office Action of August 20, 2010 provides the examination of claims 1-10, 12 and 16, claims 11 and 13-15 having been canceled by the previously filed Amendment.

Claim 1 is amended herein to incorporate recitations of claim 16, which is therefore canceled. Claim 12 is amended to conform its language to amended claim 1.

#### **Rejection under 35 USC § 112, second paragraph**

Claims 1-15 [sic. 1-10 and 12] remain rejected under 35 USC § 112, second paragraph, as being indefinite for failing to distinctly claim the invention. In particular, the Examiner maintains his position that the claim as a whole omits "essential" steps of the invention. The Examiner is not persuaded by Applicants' explanation that claim 1 as examined recited intermediate steps in an overall process of synthesis of a polymer product. The Examiner takes this explanation as an admission by Applicants that indeed an incomplete process is claimed.

As to any admission that an incomplete process is claimed, Applicants disagree. The process that is claimed can be embedded in a larger process that synthesizes a protein-polymer, but as far as the step that is the subject matter of the claim, the process that is recited is complete. The Examiner should consider that the process as claimed is a subcombination of a combination, and no essential step is omitted from the subcombination as claimed.

Furthermore, claim 1 as examined uses the transitional phrase, "comprising", thus any additional steps that the Examiner might believe must be recited to provide a "complete" process are in fact encompassed by claim 1 as examined.

Nonetheless, Applicants have amended the preamble of claim 1 to recite the preamble of claim 16, which is not included in the instant rejection. Thus, the present rejection is overcome.

Rejection under 35 USC § 112, first paragraph

Claim 16 is rejected under 35 USC § 112, first paragraph, for alleged failure of the specification to provide written description support for the claimed invention. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner asserts that the specification does not teach that a polymer is released from a protein upon reaction of a polymer-protein conjugate with a thiol exchange reagent. The Examiner points to text at paragraph [0103] of the specification, "[I]t is thought that PEG forms an unstable thioester bond with Cys playing an important role in expressing methioninase activity to decrease specific activity in a step of PEG conjugation reaction, but an exchanging reaction occurs by performing DTT treatment, and PEG-rMETase having a recovered SH group is produced." The Examiner asserts that this description indicates that PEG-METase is recovered, and so the PEG polymer is not released from methioninase by the reaction with DTT.

First, the sentence pointed to by the Examiner expressly states that a free thiol group is recovered after a PEG-thioester bond with Cys is reacted with DTT, and so Applicants do not understand at all how the Examiner can understand that the reaction recited in the claims is not described in the specification.

Furthermore, the Examiner is incorrectly interpreting the single sentence pointed out in a vacuum, rather than in the context of the specification as a whole. As pointed out in the previous Amendment, paragraph [0009] of the specification describes that the protein products produced by the method of the invention may include polymer moieties attached to the protein at sites in addition to thiol groups, for example at amino groups or carboxyl groups. The presently-claimed process is one that eliminates polymers attached at thiol groups, with the result that a PEG-protein conjugate (or other polymer-protein conjugate) having free thiol groups is obtained. The Examiner might also review, for example, paragraph [0012] of the specification, which describes production of a PEG-METase using the process of the present invention.

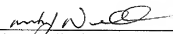
Applicants submit that the present claims clearly recite subject matter well-described in the specification. Applicants thus believe the pending application is in condition for allowance, and such favorable action is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: November 19, 2010

Respectfully submitted,

By   
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